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THE TREATMENT OF EARLY SYPHILIS BY A FIVE-WEEK PENICILLIN- MAPHARSEN-BISMUTH SCHEDULE*

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THE hope of finding a rapid cure for early syphilis was again envisioned after the publication in 1943 of the preliminary report of Mahoney and his associates dealing with the penicillin treatment of this infection. Since then numerous schedules of treatment have been tried and abandoned, while others have been kept with various modifications. It must be emphasized that all these are only in the experimental stage and are revised frequently. It will require a larger number of patients (several thousands) followed after termination of treatment during many years (a minimum of five years) to obtain a final evaluation of the efficacy of the drug and of its best mode of administration.

It is to be pointed out by the way that a physician treating a case of syphilis with penicillin has the responsibility of a prolonged post-treatment observation.

A preliminary evaluation is possible in early syphilis. It has been found that penicillin can be compared advantageously with other drugs in its action on the disappearance time of the *Treponema pallidum* from superficial lesions, the rapidity of healing of these lesions, and the serologic response. Its high value in the treatment of prenatal syphilis is also established. Among the other details of valuable information accumulated are those regarding routes of administration, total dosage, intervals between doses, length of treatment, advantages of associating chemotherapy. The association of penicillin and chemotherapy has led again to many schemes of treatment. None of them has

given yet the final answer as to which is the best method.

This is a preliminary report on a schedule of treatment which has been tried for the last 30 months on 230 patients, in the Department of Dermatology and Syphilology, Notre-Dame Hospital, Montreal.

TECHNIQUE OF TREATMENT

Treatment consists in the administration of penicillin, mapharsen and bismuth over a period of five weeks, necessitating hospitalization for the first week. During the first week, the three drugs are used simultaneously. During the four other weeks only mapharsen and bismuth are given.

TABLE I.
SCHEDULE OF TREATMENT

	<i>Penicillin</i>	<i>Mapharsen</i>	<i>Bismuth</i>
1st week	2,400,000u	4 x 0.06	2 x 0.07
2nd week	4 x 0.06	2 x 0.07
3rd week	4 x 0.06	2 x 0.07
4th week	4 x 0.06	2 x 0.07
5th week	4 x 0.06	2 x 0.07
Total	2,400,000u	1,200 mgm.	700 mgm.

Sodium penicillin in aqueous solution is administered intramuscularly every three hours, in 60 injections of 40,000 units each. A total dosage of 2,400,000 units is thus received in 7½ days. Mapharsen is given at the rate of four injections of 60 mgm. each, every week, for five weeks, the total dosage being 1,200 mgm. in twenty injections. Bismuth, in oil solution (bivatol), containing 0.07 gm. of metallic bismuth per c.c., is administered at the rate of one c.c. twice a week, for five weeks.

This total dosage of arsenobismuth therapy is higher than in most other schedules of treatment where, in association with penicillin, arsenical and bismuth preparations are usually given in sub-curative doses but in a shorter period of time. This system of treatment was designed in May, 1945, after consideration of expectation of cure, relation of dosage to duration of treatment and margin of safety. As far as the margin of safety is concerned, this was based to

* Read by Albéric Marin at the Annual Meeting of the Royal College of Physicians and Surgeons of Canada, Ottawa, November 29, 1947.

a certain extent on the experience in this clinic. Sixty cases had been treated with daily injections of mapharsen for 30 days, for a total dosage of 1,800 mgm., without any serious reaction.¹ About the same time Goldblatt reported on 107 patients treated by a similar schedule with no adverse reactions.² It was then felt that by spreading 1,200 mgm. of mapharsen over 35 days, the margin of safety would be further increased.

MATERIAL AND METHOD

In May, 1945, this schedule of treatment was adopted for treatment of cases of early syphilis. Up to November, 1947, 230 patients, all white and civilians, were placed under treatment. Of these, 222 (96%) received complete treatment. A total of 201 cases have been kept for final analysis. The 29 others were eliminated because of previous treatment, late syphilis, doubtful diagnosis, delinquency from treatment (only 2). However a woman who died is included in this group of 201, although she did not receive full treatment.

Table II shows the distribution of cases according to sex and age.

TABLE II.
DISTRIBUTION OF CASES ACCORDING TO SEX AND AGE

Age group	Male	Female	Total
14 to 19	7	28	35
20 to 24	39	41	80
25 to 29	24	17	41
30 to 34	9	11	20
35 to 39	9	4	13
40 to 49	9	1	10
50 to 59	2	0	2
Total	99	102	201

In the whole series, males and females are about in equal number. In the age group 14 to 19 there are four times as many women as men. The age group 20 to 24 is by far the largest (40%). From the age of 35 to 60, men are more numerous than women (20 against 5).

Table III shows the distribution of cases according to sex and stage of the disease.

TABLE III.
DISTRIBUTION OF CASES ACCORDING TO SEX AND STAGE OF THE DISEASE

Stage of the disease	Male	Female	Total
Primary seronegative	34	2	36
Primary seropositive	41	14	55
Early secondary (less than 6 months)	21	73	94
Early latent (less than 6 months)	3	13	16
Total	99	102	201

The primary seronegative group forms 18% of the series, which is a larger proportion than what was seen in the past in the clinic. It is to be noted that there are 34 men and only 2 women. The group of early secondary syphilis forms 47% of the series. In this group there are 3½ times more women than men (73 against 21). It may be eventually possible to see more women at an earlier stage of the disease with an intensification of the educational campaign and with more social workers who could locate at an earlier date the female sexual partners of known infected males.

Management.—In all cases of primary syphilis, the clinical diagnosis was confirmed by a positive darkfield examination and by S.T.S. (serologic tests for syphilis). In early secondary syphilis of less than 6 months, the clinical diagnosis was confirmed by S.T.S. and by darkfield examination when possible. In early latent syphilis of less than 6 months, the diagnosis was made by repeated S.T.S., careful medical history, interview of sexual contacts, and, when available, by evidence of previous negative S.T.S. a few months earlier.

Quantitative blood Wassermann tests were performed on all patients. Standard Kahn tests were made but they were not titred.* The cerebrospinal fluid was examined 6 to 12 months after treatment when possible. After completion of treatment, patients were instructed to report every week until seronegative and then once a month if progressing favourably. In some instances, when S.T.S. was not negative 6 months after treatment the patient was treated with the routine arsenobismuth method.

In tables on results of treatment, re-treatment with conventional therapy has not been taken into consideration. Re-treated patients are however tabulated amongst those progressing unfavourably.

Follow-up of patients.—Table IV shows the distribution of cases according to the date of onset of treatment and length of time that the patient has been under observation.

It is noted that of the 170 cases whose treatment was begun prior to May, 1947, 135 or 79% were observed for 6 or more months. This compares favourably with the follow-up performance of well-known clinics. It is felt that

* All serologic tests for syphilis were done at the Provincial Laboratory, Department of Health, Province of Quebec.

this would not have been possible without efficient social service workers. They are in a better position than the physician to take the necessary steps to ensure that all patients continue their treatment regularly and to prevent the less responsible ones from becoming delinquents. Their activities are also responsible for the collection of valuable medical information.

erythema on the 9th day, 7 cases of urticaria and one of angioneurotic oedema which did not delay treatment. A mild form of arsenical dermatitis delayed treatment for a week.

The case of death occurred in a woman, aged 34, weight 140 lb., apparently in good health and was due to encephalopathy. She had received in 13 days, 2,400,000 units of penicillin, six

TABLE IV.
DISTRIBUTION OF CASES ACCORDING TO DATE OF ONSET OF TREATMENT AND
LENGTH OF FOLLOW-UP BY THE SOCIAL SERVICE

Date of onset of treatment	Length of follow-up					Total number of cases
	Less than 6 months	6 to 12 months	12 to 18 months	18 to 24 months	24 to 30 months	
May, 1945 to November, 1945	2	7	5	12	8	34
November, 1945 to May, 1946	3	2	7	19	..	31
May, 1946 to November, 1946	6	19	24	49
November, 1946 to May, 1947	24	32	56
May, 1947 to November, 1947	31	31
Total	66	60	36	31	8	201

Table V shows reactions to treatment which were all minor except one case of encephalopathy with death.

TABLE V.
REACTIONS

	Male	Female	Total
Herxheimer reaction	0	2	2
Primary fever	20	24	44
Secondary fever	4	7	11
Gastro-intestinal disturbances	5	11	16
Nitritoid reaction	0	1	1
Angioneurotic oedema	1	0	1
Urticaria	3	4	7
Erythema of the ninth day	3	0	3
Arsenical dermatitis	0	1	1
Bismuth stomatitis	0	5	5
Encephalopathy with death	0	1	1
Total number of reactions	36	56	92

The minor reactions did not have an appreciable delaying action on the schedule of treatment. There were five cases of a mild form of stomatitis where the last injections of bismuth were postponed. In the 11 cases of secondary fever there was a delay of a few days. The 16 cases of gastro-intestinal disturbances were of a mild nature. Exacerbation of mucocutaneous lesions with fever was seen in two cases and classified as Herxheimer reaction. Cases showing fever within the first 24 hours of treatment were grouped under the heading of primary fever (44 cases). There was one case of mild nitritoid reaction, in midcourse of treatment, in a woman who could complete it with the addition of adrenalin. There were three cases of

injections of mapharsen and three injections of bismuth. She died two days after the last injection of mapharsen and 15 days after the beginning of treatment. During treatment she did not have primary or secondary fever, nausea, vomiting, headache, or dizziness.

The results of treatment of seronegative primary syphilis are shown in Table VI.

TABLE VI.
RESULT OF TREATMENT IN SERONEGATIVE
PRIMARY SYPHILIS

Number of cases in which the S.T.S. remained negative throughout the whole observation period	31
Number of cases in which the S.T.S. became temporarily positive or doubtful during or after treatment and subsequently became negative	5
Number of serologic relapses	0
Number of clinical relapses	0
Number of neuro-recurrences	0
Total number of cases treated	36
Percentage of successful results	100%

NOTE—Of the 36 cases, 27 (75%) were under observation for 6 or more months and 17 (47%) for 12 or more months.

There were 36 patients in this group. In 31 of these, or 86%, S.T.S. remained negative throughout the whole observation period. In the other 5 patients, S.T.S. became temporarily positive or doubtful during or after treatment and subsequently became and remained negative. In three of these S.T.S. were still negative after 12 months of observation and in the other two the tests were still negative after 18 months

of observation. There was no case of serologic relapse nor of clinical relapse in this group.

Table VII shows the result of treatment in seropositive primary syphilis according to the length of the observation period.

S.T.S. became negative in 41 (74%) of the 55 cases in this group. In all 41 cases the tests became negative in less than 6 months. They have remained negative in 32 (86%) of the 37

patients who were observed 12 or more months. S.T.S. became doubtful in 9 patients, 8 of whom have been observed less than 6 months, the other having been observed 18 months. Two patients, with less than 12 months of observation still had a positive S.T.S.

There was no case of serologic relapse without clinical signs. There was one case of clinical relapse with positive S.T.S., 5 months after

TABLE VII.
RESULT OF TREATMENT ACCORDING TO LENGTH OF FOLLOW-UP
SEROPOSITIVE PRIMARY SYPHILIS

Outcome	Number of months of follow-up										Total	
	1 to 6		6 to 12		12 to 18		18 to 24		24 to 30			
	Number of cases		Number of cases		Number of cases		Number of cases		Number of cases		Number of cases	
Becoming and remain- ing S.T.S. negative .	9	% 50	17	% 94	10	% 100	4	% 50	1	% 100	41	% 74
Becoming and remain- ing S.T.S. doubtful .	8	44	1	12	9	16
S.T.S. still positive ...	1	5	1	5	2	3
Serologic relapse
Clinical relapse	1	12	1	2
Possible reinfection	1	12	1	2
Neuro-recurrence	1	12	1	2
Total	18	100	18	100	10	100	8	100	1	100	55	100

NOTE—This table does not indicate the time at which the outcome was achieved. It shows the number of cases and the time at which the outcome was last observed.

TABLE VIII.
RESULT OF TREATMENT ACCORDING TO LENGTH OF FOLLOW-UP
(a) EARLY SECONDARY SYPHILIS

Outcome	Number of months of follow-up										Total	
	1 to 6		6 to 12		12 to 18		18 to 24		24 to 30			
	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases	Number of cases			
Becoming and remaining S.T.S. negative .	5	16	25	86	10	83	16	88	3	60	59	62
Becoming and remaining S.T.S. doubtful .	19	63	1	3	2	16	1	5	23	24
S.T.S. still positive ...	6	20	2	6	1	5	1	20	10	20
Serologic relapse	1	20	1	1
Clinical relapse
Neuro-recurrence	1	3	1	1
Total	30	100	29	100	12	100	18	100	5	100	94	100

NOTE—This table does not indicate the time at which the outcome was achieved. It shows the number of cases and the time at which the outcome was last observed.

(b) EARLY LATENT SYPHILIS

Outcome	Number of cases	
Becoming and remaining S.T.S. negative	8	50
Becoming and remaining S.T.S. doubtful	4	25
S.T.S. still positive	2	12
Serologic relapse	1	6
Fatality	1	6
Total	16	100

treatment. There was one case of possible re-infection, 3 months after treatment, the patient presenting himself with a single darkfield positive penile lesion at a site different from his initial lesion. His S.T.S. which had become doubtful, subsequently became positive. His wife was then examined and found to have secondary syphilis. This case is counted as a treatment failure in accordance with the practice of other workers in the field of intensive therapy for early syphilis. There was one case of neuro-recurrence without clinical signs, 6 months after treatment. These three cases of definite failures to treatment occurred among patients who were under observation for 18 to 24 months.

Table VIII shows the result of treatment of secondary syphilis according to the length of the observation period.

S.T.S. became negative in 59 (62%) of the 94 patients in this group. In 57 of these S.T.S.

8, became doubtful in 4 and showed no change in 2. There was one case of serologic relapse 7 months after treatment. The other patient was the case of fatality to which reference was made in a previous paragraph.

Cerebrospinal fluids after treatment.—In only 3 of the 96 patients whose cerebrospinal fluid was examined was any abnormality noted. There were 2 cases of asymptomatic neurorecurrences, one in the group of seropositive primary syphilis and the other in the group of secondary syphilis. In the first case the cerebrospinal fluid abnormalities were of group III, and in the second the abnormalities were of group II according to Moore's classification. The case of fatality, who died of encephalopathy, had group II abnormalities of the spinal fluid. Of the patients who were under observation for 6 or more months, 21 (77%) of 27 cases of seronegative primary syphilis, 26 (70%) of 37 cases of seropositive

TABLE IX.
CUMULATIVE TREATMENT RESULTS
135 CASES FOLLOWED-UP 6 OR MORE MONTHS

Outcome	Number of months of follow-up							
	6 or more		12 or more		18 or more		24 or more	
	Number of cases	%	Number of cases	%	Number of cases	%	Number of cases	%
Becoming and/or remaining S.T.S. negative .	116	85.0	62	82.0	30	76.0	6	75.0
Becoming and remaining S.T.S. doubtful ...	8	5.0	7	9.0	3	7.0
S.T.S. still positive	5	3.0	2	2.0	2	5.0	1	12.0
Serologic relapses	2	1.5	1	1.3	1	2.5	1	12.0
Clinical relapse	1	0.7	1	1.3	1	2.5
Possible reinfection	1	0.7	1	1.3	1	2.5
Neuro-recurrences	2	1.5	1	1.3	1	2.5
Total	135	100	75	100	39	100	8	100

became negative in less than 6 months and in the other two in less than 9 months. S.T.S. have remained negative in 54 (84%) of the 64 patients who were observed 12 or more months. S.T.S. became doubtful in 23 cases, of which 19 were observed less than 6 months and 4 were observed from 6 to 24 months. Ten patients still had positive S.T.S. Two of these can be considered as seroresistant since they were observed more than 12 months. There was one case of serologic relapse without clinical signs 5 months after treatment. There was no cause of clinical relapse nor of possible reinfection. There was one case of neurorecurrence without clinical signs, 10 months after treatment.

Early latent syphilis.—There were only 16 cases of early latent syphilis of less than 6 months' duration. S.T.S. became negative in

primary syphilis, 40 (62%) of 64 cases of secondary syphilis and 6 (36%) of 16 cases of early latent syphilis had a normal cerebrospinal fluid.

Table IX shows the cumulative results of treatment in the 135 cases of all diagnosis who have been followed-up for 6 or more months.

It is noted that 85% of the cases had seronegative tests after 6 months, 82% after 12 months, 76% after 18 months and 75% after 24 months. The percentage of patients with seropositive tests increases from 3% after 6 months to 12% after 24 months. Also the percentage of definite treatment failures increases from 4% after 6 months to 12% after 24 months. It would therefore appear that with the passage of time the treatment results become less satisfactory. However the number of cases followed-up for 18 months and more is rather small (39)

and these percentages may not be altogether significant.

Table X shows the summary of the results of treatment.

(a) *Satisfactory progress*.—All cases of seronegative primary syphilis were still seronegative at the time of last examination, a satisfactory result in 100% of cases. In seropositive primary syphilis, S.T.S. had become and remained negative in 74% of the patients and doubtful in 16%, for a total of 90% of satisfactory progress. In secondary syphilis, 86% of the patients were progressing favourably. The overall results show 72% of seronegativity and an additional 18% of doubtful serology for a total of 90% of satisfactory progress.

(b) *Treatment failures*.—The definite failures from treatment included one case of clinical

with the 20 day intensive arsenobismuth system (1,200 mgm. mapharsen and 8 injections of bismuth subsalicylate). Steinberg and Leifer³ reporting on the results of treatment of early syphilis with penicillin alone, with an observation period of more than 9 months in over 80% of the cases, obtained satisfactory progress in 94% of the primary seronegative cases, in 89% of primary seropositive cases, and in 83% of early secondary. Pillsbury⁴ reporting on the results in early syphilis treated by the twenty-day system, with an observation period of 12 months, found a negative S.T.S. in 97% of the primary seronegative syphilis, in 93% of primary seropositive, in 95% of secondary syphilis.

With the five-week treatment reported in this paper, of the patients followed-up for 6 months or more, S.T.S. was negative in 100%

TABLE X.
RESULT OF TREATMENT—SUMMARY

	<i>Seronegative primary syphilis</i>		<i>Seropositive primary syphilis</i>		<i>Secondary syphilis</i>		<i>Early latent syphilis</i>		<i>All cases</i>	
	<i>Number of cases</i>		<i>Number of cases</i>		<i>Number of cases</i>		<i>Number of cases</i>		<i>Number of cases</i>	
S.T.S. negative	36	% 100	41	% 74	59	% 62	8	% 50	144	% 72.0
S.T.S. doubtful	9	16	23	24	4	25	36	18.0
S.T.S. positive	2	3	10	10	2	12	14	7.0
Serologic relapses	1	1	1	6	2	1.0
Clinical relapses	1	2	1	0.5
Possible reinfection	1	2	1	0.5
Neuro-recurrence	1	2	1	1	2	1.0
Fatality	1	6	1	0.5
Total	36	100	55	100	94	100	16	100	201	100

relapse with positive S.T.S., one case of possible reinfection, two cases of serologic relapses without clinical signs, cases of neurorecurrences, two cases of seroresistance after one year and one case of fatality, a total of 9 cases (4.5%).

(c) *Results pending*.—The other 12 patients still had a positive serologic test at the time of last examination. Half of these were cases of secondary syphilis who have been under observation for less than 6 months. Some of the others were given retreatment after only 6 months of follow-up and it will not be easy to determine whether they will have to be considered as failures or not.

COMMENT

The five-week treatment reported in this paper may be compared with the treatment by penicillin alone (2.4 million in 7½ days) and

of cases of primary seronegative, in 86% of primary seropositive, in 84% of secondary syphilis. It would appear that the results obtained by the 20-day system are superior and that the results of the treatment by penicillin alone are about equal to those obtained with the five-week schedule. The results of the five-week schedule may be improved later when a larger number of patients will have been treated and followed-up.

There was one case of death, the 162nd case, who died after having received 360 mgm. of mapharsen in 13 days. Apart from this there was not a single severe toxic reaction.

The toxicity of a scheme of treatment is measured by the incidence of severe toxic reactions, accompanied or not by death. Heller⁵ reported one death and over 30 severe toxic reactions per 4,312 patients treated with penicillin

combined with small amounts of mapharsen and bismuth. It rather seems that in the five-week system it was an unfortunate hazard that the only case of severe toxic reaction was a fatality and therefore it was felt that the continuation of this method of therapy was justifiable.

SUMMARY

1. This is a preliminary report on 201 cases of early syphilis treated by a five-week penicillin-mapharsen-bismuth schedule.

2. Of 230 patients who started on this schedule, 96% received the complete treatment. Twenty-nine were not considered in this study mainly because they were not definitely cases of early syphilis.

3. It has been possible to keep under observation for 6 or more months 79% of the patients treated prior to May, 1947.

4. There was one fatality due to encephalopathy (0.4%) and there were no other severe toxic reactions.

5. Satisfactory progress was obtained in 100% of 36 cases of seronegative primary syphilis, in 90% of 55 cases of seropositive primary syphilis, and in 86% of 94 cases of secondary syphilis.

6. The overall results show 90% of satisfactory progress and 4.5% of definite treatment failures, with the other 6% pending. If results obtained so far are maintained, the five-week schedule will compare favourably with other adequate treatment methods for early syphilis.

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RÉSUMÉ

Rapport préliminaire des résultats obtenus chez 201 malades atteints de syphilis précoce et traités par l'association P.M.B. en séries conjuguées pendant 5 semaines. Sur 230 malades inscrits au début, 90% reçurent le traitement complet. 29 ont été rayés de la série parce qu'ils ne répondaient pas exactement à la définition de syphilis précoce. 76% des malades traités avant mai 1947 ont été suivis pendant 6 mois et davantage. On n'a relevé qu'une seule mortalité, par encéphalite, soit 0.4% du total. Par ailleurs on ne nota aucune réaction sérieuse.

Des résultats excellents ont été relevés dans 100% des 36 cas de syphilis primaire séro-négative, dans 90% des 55 cas de syphilis primaire séro-positif, et dans 86% des 94 cas de syphilis secondaire. Dans l'ensemble 90% ont eu des résultats satisfaisants et 4.5% furent des échecs; 6% ne sont pas classés définitivement. Si les résultats obtenus persistent, ce traitement de 5 semaines supportera avantageusement la comparaison avec tout autre mode de traitement de la syphilis précoce.

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THE PROBLEM OF THE OLDER AGE HERNIA

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IN a recent summary and subsequent survey of 522 herniotomies of all types representing the surgical repairs done on the Surgical Service of Shaughnessy Hospital during the period from October 1, 1945 to September 30, 1947, an effort was made to break down and tabulate the results in a variety of ways. In so doing, some interesting figures presented themselves in respect to the various age groups. We immediately became interested in the older age group, namely 60 years and older, and of the total number of 552, it was noted that 50 came into this age group, a percentage of 9.05.

The youngest was naturally 60, the oldest 87—giving an average age of 64.

Types of hernia

Indirect inguinal	18
Direct inguinal	26
Direct and indirect	4
Strangulated	1
Incarcerated	3
Bilateral	5
Recurrent	4
Femoral	2
Strangulated	2

Types of repair

Halstead	22
Bassini	19
Ferguson	2
McArthur	2
Henry	2
Simple ligation of sac	1
La Roque	1
Mattson	1

Suture material

Steel	39
Silk	6
Fascia	2
No repair	3

Ambulation started postoperatively

Shortest	1
Longest	14
Average	1.9

Postoperative days—hospital

Shortest	9
Longest	29
Average	14.4

Total postoperative treatment days

Shortest	10
Longest	55
Average	30.4